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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,152	12/31/2001	Mian-Ying Wang	10209.383	3964

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EXAMINER	
COE, SUSAN D	
ART UNIT	**PAPER NUMBER**
1654	6

DATE MAILED: 04/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,152	WANG ET AL.	
	Examiner	Art Unit	
	Susan Coe	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The preliminary amendment filed April 29, 2002 has been received and entered.

2. Claims 1-32 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-23, 27, 28, 31, and 32 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the claimed conditions, does not reasonably provide enablement for preventing the claimed conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The claims are directed towards "preventing" liver related disorders and cancers; however, the specification is not considered to provide enablement for preventing these diseases. In order to be enabled for prevention, the specification would have to show that the claimed composition would be able to prevent the claimed disorders and cancers in each and every

instance of the diseases. The causes of these diseases is extremely varied and unpredictable. Therefore, an artisan of ordinary skill in the art would be forced to experiment unduly in order to determine if the invention functions as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 31 is considered indefinite because the claim does not state what the method is inhibiting or preventing the hepatic carcinogens from doing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-22 and 24-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Pat. Appl. No. 08217686 A.

JP '686 teaches administering *Morinda citrifolia* to treat hepatitis and hepatic cancer caused by *Helicobacter pylori* (see English abstract). The reference does not specifically state that the composition prevents cancerous growth by blocking carcinogen-DNA adduct formation.

However, since the reference composition is able to treat the same cancer as that claimed by applicant, the reference composition is considered to have this property.

The reference does not specifically teach administering the claimed composition in the amounts and for the periods of time claimed by applicant. The dosage amount of a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal dosage amount of the active ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

6. Claims 1-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 88/05304.

WO '304 teaches administering *Morinda citrifolia* to treat viral hepatitis (see first paragraph of page 3). The reference does not specifically teach administering the claimed

composition in the amounts and for the periods of time claimed by applicant. The dosage amount of a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal dosage amount of the active ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

The reference also does not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the reference in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the reference in the forms claimed by applicant.

7. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 4,039,559 and US Pat. Appl. No. 2002/0068102 A1 (effective filing date December 1, 2000).

US '559 teaches that carbon tetrachloride causes liver damage due to its ability to produce harmful free radicals. The reference uses a free radical scavenger to treat this damage (see column 4, lines 3-23). The reference does not specifically teach using *Morinda citrifolia* as the free radical scavenger. However, US '102 teaches a *M. citrifolia* composition that is a free radical scavenger (see paragraph [0014]). Therefore, based on the disclosures by the references,

a person of ordinary skill in the art would reasonably expect that *M. citrifolia* would be able to treat liver damage caused by exposure to carbon tetrachloride because it is an antioxidant. Thus, an artisan of ordinary skill in the art would be motivated to use *M. citrifolia* to treat liver damage caused by exposure to carbon tetrachloride.

The references do not specifically teach administering the claimed composition in the amounts and for the periods of time claimed by applicant. The dosage amount of a pharmaceutical composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal dosage amount of the active ingredient in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of dosage amount would have been obvious at the time of applicant's invention.

The references also do not specifically teach administering the composition in the forms claimed by applicant. These forms of administration are well known in the art to be acceptable means of administering a pharmaceutically active substance. Based on this knowledge, a person of ordinary skill in the art would have had a reasonable expectation that administering the composition taught by the references in the claimed forms would be successful. Therefore, an artisan of ordinary skill would have been motivated to administer the composition taught by the references in the forms claimed by applicant.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
April 10, 2003